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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/658,734      | 09/11/2000  | Winfried Edelmann    | AHN-001DV1          | 9039             |

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BOSTON, MA 02109

EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/22/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/658,734

Applicant(s)

EDELMANN ET AL.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13,14 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13,14 and 22-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election of group I, claims 13 – 14 and 22 in paper No.7 is acknowledged.

Upon review of the claims and reasons for traverse, the restriction requirement has been withdrawn. Claims 13 – 14 and 22 – 29 are pending and have been considered on the merits.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13 – 14 and 22 – 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13 – 14 and 22 – 29 are drawn to a method for identifying a compound, however are rendered vague and indefinite because the claim appears to omit essential steps in the method. It is unclear how one would identify a compound which modulates by simply determining the effect of the compound. Moreover, it is unclear what effects, observations or demonstrations must occur to thereby identify the compounds which do or do not modulate MSH5 activity. As stated, it would appear that any test compound would modulate MSH5 activity. For example, after contacting a test compound with MSH5 and determining the effect,

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the compound has been identified as one which modulates the activity, regardless of whether the compound inhibits, stimulates or has no effect on MSH5 activity.

Claim 23 is rendered vague and indefinite for reciting “capable of” because the phrase fails to define if the recited functional effect actually occurs or not. For example, MUST the compound modulate MSH5 expression, or merely have the potential to modulate MSH5 expression.

Claim 29 is rendered indefinite for reciting “has an effect” because it is unclear what the effect must be. For example, is the substrate is inhibited, stimulated, destroyed, deactivated?

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 13 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Fishel et al. (US 6333153).

Applicant claims a method for identifying a compound which modulates MSH5 activity, the method comprising a) contacting MSH5 with a test compound, and b) determining the effect of the test compound on the activity of MSH5, wherein the compound is capable of modulating MSH5 expression.

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Fishel teaches a method for determining if a composition affects (or modulates) expression of a gene encoding a MutS homolog (MSH) (col.9 line 10-15) wherein the MutS homolog may be MSH5 (col.4 line 35-40). The method comprises administering the test composition (or compound) to a cell containing the MutS homolog (or MSH5) and a cell which does not contain the MutS homolog followed by observing phenotypic effects on the cells to determine if the compound effects (or modulates) MutS homolog activity (col.9 line 29-45).

The reference anticipates the claimed subject matter.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claims 13 – 14 and 23 – 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishel et al. (US 6333153) in view of Tartaglia et al. (US 5972621).

Applicant claims a method for identifying a compound which modulates MSH5 activity, the method comprising a) contacting MSH5 with a test compound, and b) determining the effect of the test compound on the activity of MSH5. Specifically, the compound inhibits MSH5 activity, is capable of modulating MSH5 expression, is an antisense MSH5 nucleic acid, small molecule, MSH5 antibody, peptide, peptidomimetic, or has an effect on an MSH5 substrate.

Fishel teaches a method for determining if a composition affects (or modulates) expression of a gene encoding a MutS homolog (MSH) (col.9 line 10-15) wherein the MutS homolog may be MSH5 (col.4 line 35-40). The method comprises administering the test composition (or compound) to a cell containing the MutS homolog (or MSH5) and a cell which does not contain the MutS homolog followed by observing phenotypic effects on the cells to determine if the compound effects (or modulates) MutS homolog activity (col.9 line 29-45).

Fishel does not teach the method wherein the test compound inhibits MSH5 activity, is an antisense nucleic acid molecule, small molecule, antibody, peptide, peptidomimetic or has an effect on MSH5 substrate. However, Tartaglia teaches methods for identifying compounds that modulate gene expression and/or gene product activity (col.6 line 1-5) wherein the screened compounds include peptides, antibodies, peptidomimetics, small organic molecules, agonists and antagonists of the gene (col.29 line 27-52). Although Tartaglia does not specifically teach antisense nucleic acids used as the test compound, the reference does teach compounds can be small molecules that affect gene expression (col.29 line 52-61). At the time of the invention, it

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was well known in the art that antisense nucleic acids inhibit gene expression (see “Antisense Nuclei Acid for Therapeutic and Other Applications, 1998, p.1).

At the time of the claimed invention, one of ordinary skill in the art would have been motivated use the claimed compounds in the methods of Fishel because they were routinely used in the art in such methods as evidenced by Tartaglia. Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated to use the aforementioned compounds in the methods of Fishel with a reasonable expectation for successfully identifying if the compound modulates MSH5 activity.

8. Claims 13 – 14 and 23 – 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartaglia et al. (US 5972621).

Applicant claims a method for identifying a compound which modulates MSH5 activity, the method comprising a) contacting MSH5 with a test compound, and b) determining the effect of the test compound on the activity of MSH5. Specifically, the compound inhibits MSH5 activity, is capable of modulating MSH5 expression, is an antisense MSH5 nucleic acid, small molecule, MSH5 antibody, peptide, peptidomimetic, or has an effect on an MSH5 substrate.

Tartaglia et al. teaches methods for identifying compounds that modulate gene expression and/or gene product activity (col.6 line 1-5). Specifically, the methods identify compounds that interact with a gene or proteins that interact a gene (or a substrate), compounds that modulate the gene activity and/or gene levels and/or gene expression (col.29 line 10-25) and compounds that disrupt (or inhibit) normal gene interactions (col.31 line 40-50). The compounds to be screened include peptides, antibodies, peptidomimetics, small organic molecules, agonists and antagonists

of the gene (col.29 line 27-52). The method comprises preparing a reaction mixture of the gene and test compound (or contacting the gene and test compound) followed by detecting gene/test compound complexes (which determines an effect on the gene) (col.31 line 49 - col.32).

Tartaglia does not teach the methods wherein the gene is MSH5. However, at the time of the invention, it would have been obvious to one of ordinary skill in the art to use any gene in the methods Tartaglia because they were well known processes in the art as evidenced by Tartaglia. Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated to practice the methods of Tartaglia with MSH5 with a reasonable expectation for successfully identifying compounds that modulate MSH5 activity.

Although Tartaglia does not specifically teach antisense nucleic acids used as the test compound, the reference does teach compounds can be small molecules that affect gene expression (col.29 line 52-61). At the time of the invention, it was well known in the art that antisense nucleic acids inhibit gene expression (see "Antisense Nuclei Acid for Therapeutic and Other Applications, 1998, p.1). Therefore, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to test an antisense nucleic acid of the target gene in the methods of Tartaglia with a reasonable expectation for successfully identifying if the compound modulates the target gene's activity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

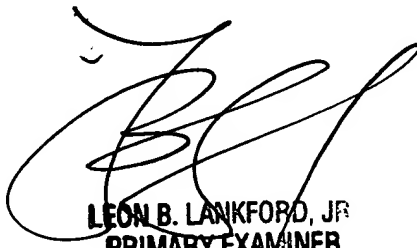


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad  
April 15, 2002



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER